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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,529	05/10/2002	Achim Berthold	512100-2025	6199

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EXAMINER	
GHALI, ISIS A D	
ART UNIT	PAPER NUMBER
1615	
MAIL DATE	DELIVERY MODE
07/24/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/031,529	BERTHOLD ET AL.	
	Examiner	Art Unit	
	Isis A. Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05/29/2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' amendment and request for RCE, both filed 05/29/2007.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114 was filed in this application after a decision by the Board of Patent Appeals and Interferences, but before the filing of a Notice of Appeal to the Court of Appeals for the Federal Circuit or the commencement of a civil action. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 05/29/2007 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 25 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims fails to further limit claim 13.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 13-23, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,045,553 by Ueda et al. ('553) combined with US 4,879,119 by Konno et al. ('119) and EP 439430 ('430).

US '553 teaches a pharmaceutical composition for percutaneous drug absorption comprising dihydropyridine compound to treat hypertension and angiopathy (abstract; col.1, lines 34-37). The composition is included in a patch comprising a support

member, drug-containing layer, and release controlling membrane (col.2, lines 35-40; figures 1-6; col.4, line 12). The patch further comprises skin adhesive layer (col.3, lines 49-50; figure 2). The composition comprising nilvadipine in an amount of 5% by weight, unsaturated fatty acid, and pyrrolidone derivative (col.2, lines 45-61; col.4, lines 49-50; examples).

The reference does not teach the specific pyrrolidone derivatives, sorbitan palmitate as specific enhancers, or lacipidine and nifedipine species of dihydropyridines. The reference does not teach specific amounts of different ingredients as claimed.

It is within the skill in the art to replace one species by another known to perform the same function. Thus, claiming lacipidine or nifedipine does not render the claim patentable, absent evidence to the contrary.

The amounts of different ingredients do not impart patentability to the claims, absent evidence to the contrary.

US '119 teaches a skin patch having good transdermal properties showing increased skin penetration rate of the drug and an increased drug releasing rate (abstract; col.1, lines 9-12). The good transdermal properties are provided by a patch comprising a solution comprising the drug and penetration enhancer, such as sorbitan middle chain fatty acid ester (abstract; col.3, lines13-15). Drugs suitable for delivery by those patches are nicardipine and nifedipine dissolved in ethanol, N-methyl-2-pyrrolidone or mixture thereof (col.2, lines 33-34; col.49-58).

Thus, it would have been obvious to one having ordinary skill in the art a the time of the invention to provide a transdermal patch comprising reservoir comprising

dihydropyridine, ethanol, and penetration enhancer as disclosed by US '553, and select sorbitan ester as an enhancer as disclosed by US '119, motivated by the teaching of US '119 that a patch with such ingredients has good transdermal properties showing increased skin penetration rate of the drug and an increased drug releasing rate, with reasonable expectation of having a transdermal drug delivery device to deliver dihydropyridine in a reservoir comprising ethanol, pyrrolidone derivative and sorbitan ester that deliver the drug to the patient in need with great success.

The combination of the references does not teach the administration rate and the patch area as claimed by claims 1 and 25.

The patch delivered from the combination of US '553 and US '119 having the same ingredients as instantly claimed is expected to provide the same delivery rate. One having ordinary skill in the art would have determined the delivery rate and would have adjusted it and also adjusted the size of the patch according to specific patient conditions.

Although the combination of US '553 and US '119 teaches skin contact adhesive layer, however, the combination of references does not specifically teach the specific adhesives as claimed by claims 13 and 19.

EP '430 teaches transdermal patch to deliver dihydropyridine comprising skin contact adhesive layer made of dermatologically suitable adhesives including acrylic adhesive (page 4, lines 28-40).

Therefore, it would have been obvious to one having ordinary skill in the art a the time of the invention to provide a transdermal drug delivery device comprising a

reservoir comprising dihydropyridine, ethanol, pyrrolidone derivative and sorbitan ester and comprising skin contact adhesive layer as disclosed by the combined teaching of US '553 and US '119, and use acrylic adhesive for the skin contact adhesive layer as disclosed by EP '430 because EP '430 teaches acrylic adhesives as dermatologically suitable adhesives, with reasonable expectation of having transdermal drug delivery device comprising a reservoir comprising dihydropyridine, ethanol, pyrrolidone derivative and sorbitan ester and comprising acrylic skin contact adhesive layer that is dermatologically safe and acceptable.

Therefore, the invention as a whole is taught by the combined teaching of the references.

7. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of US '553, US '119 and EP '430, and further in view of US 5,744,162 ('162).

The combined teachings of the references are discussed previously as set forth in this office action.

However, the combination of the references does not specifically teach limonene in the composition.

US '162 disclosed transdermal device to deliver drugs including nifedipine, wherein the drug containing layer comprises limonene because it is one of the preferred permeation enhancer (abstract; col.4, line 43; col.5, lines 18-36).

Therefore, it would have been obvious to one having ordinary skill in the art a the time of the invention to provide a transdermal drug delivery device comprising a reservoir comprising dihydropyridine, ethanol, pyrrolidone derivative and sorbitan ester and comprising acrylic skin contact adhesive layer as disclosed by the combined teaching of US '553, US '119 and EP '430, and further add limonene to the composition of the reservoir as disclosed by Us '162 because US '162 teaches that limonene is one of the preferred transdermal permeation enhancer, with reasonable expectation of having transdermal drug delivery device comprising a reservoir comprising dihydropyridine, ethanol, limonene, pyrrolidone derivative and sorbitan ester wherein the reservoir has enhanced permeation of the drug through the skin.

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 4,983,395 discloses a transdermal drug delivery device comprising a drug formulation containing reservoir defined by a backing layer and a drug permeable membrane layer, and a peelable release liner (abstract; col.2, lines 30-57). The reservoir comprises ethanol, enhancer, and nicardipine (col.7, lines 55-60). The reference disclosed nifedipine as one of the dihydropyridines that are suitable to be included in the reservoir (col.5, line 25).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis A Ghali
Primary Examiner
Art Unit 1615

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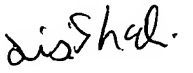

ISIS GHALI
PRIMARY EXAMINER